IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Franklin H. Portugal

Examiner: J. Souaya

Serial NO:: 09/027,439

Group Art Unit: 1634

Filed: February 20, 1998

Title: COMPOSITIONS AND METHODS FOR DIFFERENTIATING AMONG SHIGELLA SPECIES AND SHIGELLA FROM E. COLI SPECIES

SUBSTITUTE BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal filed August 1, 2003, and in response to the Notification of Non-Compliance dated December 24, 2003, attached herewith are three copies of Appellants Substitute Brief on Appeal. A fee of $55.00 for the extension of the period an additional month from the notification of Non-Compliance is enclosed. If further extension fees are necessary, the Commissioner is authorized to charge deposit account 13-3402. The statutory fee of $165.00 was submitted with the original brief.

(I) Real Parties in Interest

The real parties in interest are Franklin H. Portugal and Cabtech Inc, both of 9105 Fall River Lane, Potomac MD 20854. This is not reflected in the assignment records. An assignment from three of the four originally named inventors to the University of Maryland System, is of record. On May 17, 2001, the University of Maryland gave notice to these inventors that the University's rights in the invention would be transferred to Cabtech , Inc (see attachment B).

(II) Related Appeals and Interferences

There are no appeals or interferences known to Appellant or Appellant's legal representative which will be directly effected by or have any bearing on the Boards decision in the pending appeal.

(III) Status of the Claims

Claims 21-36, 47, 48, and 52, 53 and 55-58 are pending in this application. Claims 21-36 are withdrawn from consideration. Claims 47, 48 and 53, and 55-58 are rejected and are the subject of this Appeal. Claim 52 has been allowed. The claims on Appeal and allowed claim 52 are attached hereto as Appendix A.

(IV) Status of Amendments After Final

An amendment after final was submitted on November 3, 2003, but not entered. An Amendment After Final canceling claim 54 has been filed simultaneously with this Brief.

(V) Summary of the Invention

The invention claimed relates to nucleic acid molecules such as probes used to discriminate between *Shigella* and *E-coli* bacteria and allow identification of *Shigella* species present in a test sample. See Summary of the Invention, page 5, lines 25-30. The application describes and claims isolated nucleic acid molecules of SEQ ID NOS: 3, 4, 5 and 6, RNA equivalents thereof, and nucleic acids complementary to these isolated molecules. See table 1, page 12; page 13, lines 2-9 and page 14, lines 7-14. The application also includes claims to probes (claims 55-58) which target *Shigella flexneri, Shigella sonnei, Shigella dysenteriae, or Shigella boydii.* See page 11, lines 5-12. The probes comprise (or consist of) a fragment of more than 10 bases in length, up to 40 bases in length of nucleotide sequence SEQ ID NO: 3, 4, 5 or 6, or RNA equivalents thereof or nucleic acids complementary thereto. See page 16, lines 21-23 and lines 27-28.

(VI) Issues

1. Whether the disclosure satisfies the requirements of 37 C.F.R. §1.821(d).
2. Whether claim 58 satisfies the requirements of 37 C.F.R. §1.75(c).
3. Whether claims 55-58 define statutory subject matter and satisfy the requirements of 35 U.S.C §101.
4. Whether claims 55-58 are sufficiently definite to satisfy the requirements of 35 U.S.C §112, second paragraph.
5. Whether claims 47, 48, 53 and 55-58 are anticipated by Hogan (U.S. Patent NO: 5,541,308).
6. Whether claims 47, 48, 53 and 55-58 are anticipated by Chembank Accession NOS: X96964 or X80726 disclosed in Cilia, et. al..
7. Whether claims 47, 48, 53 and 55-58 are obvious in view of Accession NO: A14565 in view of Dyson (New Jersey) Essential Molecular Biology, Vol. II: A Practical Approach, chapter 5, pages 111-156, Brown, T.A. Ed., Oxford Press, Oxford, 1992.

(VII) Grouping of Claims

The claims herein do not stand or fall together with respect to any of the above issues.

(VIII) Arguments

Issue 1: Whether the disclosure satisfies the requirements of 37 C.F.R. §1.821(d).

Appellants maintain the specification conforms to the requirements of 37 C.F.R. §1.184(d) which is repeated below.

> d) Where the description or claims of a patent application discuss a sequence that is set forth in the ''Sequence Listing'' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by ''SEQ ID NO:'' in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The sequences referred to in Table II are preceded by SEQ ID NOS: for their first

occurrence. This satisfies the literal requirements of the rule. The rule does not require SEQ ID NOS: be repetitively provided in each instance that reference is made to a sequence in the sequence listing. Inserting the additional SEQ ID NOS: here does not help one skilled in the art to understand the invention. The sequences are clearly identified by comparison to a preceding sequence with a SEQ ID NO:

Issue 2: Whether claim 58 satisfies the requirements of 37 C.F.R. §1.75(c).

Appellants maintain claim 58 does further limit the subject matter of claim 56, the claim upon which it depends. As a dependent claim, claim 58 must be construed to incorporate all the limitations of claim 56, including the limitation that the probe defined consists of a fragment from greater than 10 bases in length to 40 bases in length of a nucleotide sequence of SEQ ID NOS: 3, 4, 5 or 6. The term "comprises 15-25 bases in length" serves to modify this range. It cannot expand the scope of the range to encompass probes longer than those defined in claim 56. The claim further limits the subject matter of claim 56 in defining probes with a minimum of 15 bases in length.

Issue 3: Whether claims 55-58 define statutory subject matter and satisfy the requirements of 35 U.S.C §101.

Appellants maintain claims 55-58 do define statutory subject matter under 35 U.S.C §101 repeated below.

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 55-58 define probes which are compositions of matter which are useful as investigative tools and clearly fall within the subject matter defined by the statute. The rejection is based on the allegation that the claims define subject matter found in nature. No evidence has been presented that these probes exist in nature. Where a molecule used as a probe is found in nature,

it is relevant as prior art under 35 U.S.C. §§102 and 103. No evidence has been presented that any of the probes claimed are anticipated or obvious based on full nucleic acid sequences found in nature.

Claims 55-58 define probes of varying length and so inherently are distinguished differently from the any subject alleged to be found in nature. No evidence has been presented of the subject matter found in nature so a comparison to each claim cannot be made.

Issue 4: Whether claims 55-58 are sufficiently definite to satisfy the requirements of 35 U.S.C §112, second paragraph.

Appellants maintain that claims 55-58 are sufficiently definite to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, and thus satisfy the requirements of 35 U.S.C §112, second paragraph. The Examiner objects to the phrase "greater than 10 to 40 bases in length" and alleges it is not clear if a nucleic acid of 15 bases in length would meet the limitations. This language can only be interpreted to define a range having a lower limit of greater than 10 bases in length , i.e. 11 bases in length, and an upper limit of 40 bases in length. Therefore, this language is not indefinite. Such an interpretation is even more certain in view of the disclosure within the specification that appears on page 16, where fragments "between about 10 and about 40 nucleotides" are said to "generally find use in hybridization embodiments." Here the range is said to include "10", therefore one skilled in the art would recognize "greater than 10" would encompass a nucleic acid of 15 bases. Therefore, with or without reference to the specification, claims 55-58 satisfy the requirements of 35 U.S.C §112, second paragraph.

The range recited in the context of "consisting of" fragment greater than 10 to 40 bases in length", is more definite in claim 56.

Claims 57 and 58 do not recite the objectionable language.

Issue 5: Whether claims 47, 48, 53 and 55-58 are anticipated by Hogan (U.S. Patent NO: 5,541,308).

Appellants maintain claims 47, 48, 53 and 55-58 are not anticipated by the disclosure within U.S. Patent NO: 5,541,308 issued to Hogan. It is alleged that Hogan teaches a probe which has complementary sequences of different portions of SEQ ID NO: 3, 4, 5 and 6. Appellants maintain providing a complementary sequence to only a portion of SEQ ID NOS: 3, 4, 5 and 6 does not anticipate the molecules and probes of claims 47, 48, 53 or 55-58.

Issue 6: Whether claims 47, 48, 53 and 55-58 are anticipated by Chembank Accession NOS: X96964 or X80726 disclosed in Cilia, et. al..

Claims 47, 48, 53 and 55-58 are rejected on the basis that the complementary sequence of SEQ ID NO: 4 is allegedly anticipated by the disclosure by Cilia et al of the sequences of Accession NOS: X96964 or X80726. As the examiner acknowledges, the accession numbers do not recite the complement and therefore, they cannot anticipate any of the complementary sequences claimed herein.

Issue 7: Whether claims 47, 48, 53 and 55-58 are obvious in view of Accession NO: A14565 in view of the Dyson Publication

These combined teachings do not show or suggest SEQ ID NOS: 3, 4, 5 or 6 and therefore they do not show or suggest their complements (capable of base-pairing according to the standard Watson-Crick complementarity rules) or their substantial complements capable of hybridizing under the conditions specified in the claim. The Examiner has interpreted the recitation of "complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules" to not require completely complementary sequences although this is clearly intended in that claims 47 and 48 define "substantially complementary" sequences in a separate paragraph. The recitations would be redundant if both defined complementary sequences which were not complete. Claims 53, and 55-58 recite the same phrase that appears in claims 47 and 48 and this phrase would have an identical interpretation. Appellant submits there is no evidence it would be obvious to prepare a sequence completely complementary or substantially complementary to SEQ ID NOS: 3,4,5 or 6 and

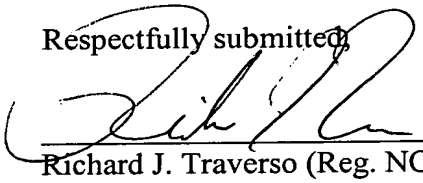
therefore, these claims have not been shown to be prima-facie obvious.

Regardless of the scope of the terms "complementary" and "substantially complementary", the references do not disclose complementary sequences of the accession numbers described and no evidence of motivation to prepare such complementary sequences has been presented. The examiner relies on hindsight to reconstruct Appellant's invention, which cannot properly support a rejection, under 35 U.S.C. §103.

(IX) Conclusion

For the reasons stated above, Appellants respectfully submit the subject matter of the pending claims is novel and unobvious over the cited references and the specification in claims satisfy the requirements of 35 U.S.C §112, first and second paragraph. Therefore, Appellants respectfully request the outstanding rejections be reversed.

Respectfully submitted,



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Attorney Docket NO:: CABTEC-2

Date: February 2, 2004

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APPENDIX

47. An isolated nucleic acid molecule comprising SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,

or an RNA equivalent thereof,

or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or a nucleic acid substantially complementary to said isolated molecule which is capable of hybridizing to the nucleic acid molecule under the following stringent conditions:

hybridization at 40°-65 °C for 14-16 hours in a hybridization solution at ph 7.8,

containing 0.9 M NaCl, 0.12 M Tris-HCl, 6nM EDTA, 0.1M sodium phosphate buffer,

0.1% SDS and 0.1% polyvinylpyrrolidone,

followed by three 15-minute washes at 40°-65 °C to remove unbound probes in a solution at pH 7, containing 0.075 M NaCl, 0.0075 M Na Citrate and 0.1% SDS.

48. An isolated nucleic acid molecule consisting of

SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,

or an RNA equivalent thereof,

or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or a nucleic acid substantially complementary to said isolated molecule which is capable of hybridizing to the nucleic acid molecule under the following stringent conditions:

hybridization at 40°-65 °C for 14-16 hours in a hybridization solution at ph 7.8, containing 0.9 M NaCl, 0.12 M Tris-HCl, 6nM EDTA, 0.1M sodium phosphate buffer, 0.1% SDS and 0.1% polyvinylpyrrolidone,

followed by three 15-minute washes at 40°-65 °C to remove unbound probes in a solution at pH 7, containing 0.075 M NaCl, 0.0075 M Na Citrate and 0.1% SDS.

52. The isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ

ID NO: 6.

53. An isolated nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,
or an RNA equivalent thereof,
or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

55. A probe which

a) targets *Shigella flexneri* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 3, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

b) targets *Shigella sonnei* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 4, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

c) targets *Shigella dysenteriae* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 5, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or

d) targets *Shigella boydii* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 6, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

56. A probe which

a) targets *Shigella flexneri* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 3, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

b) targets *Shigella sonnei* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 4, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

c) targets *Shigella dysenteriae* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 5, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or

d) targets *Shigella boydii* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 6, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

57. A probe as in claim 55 which comprises 15-25 bases in length.

58. A probe as in claim 56 which comprises 15-25 bases in length.

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1. Whether the disclosure satisfies the requirements of 37 C.F.R. §1.821(d).
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4. Whether claims 55-58 are sufficiently definite to satisfy the requirements of 35 U.S.C §112, second paragraph.
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Appellants maintain claim 58 does further limit the subject matter of claim 56, the claim upon which it depends. As a dependent claim, claim 58 must be construed to incorporate all the limitations of claim 56, including the limitation that the probe defined consists of a fragment from greater than 10 bases in length to 40 bases in length of a nucleotide sequence of SEQ ID NOS: 3, 4, 5 or 6. The term "comprises 15-25 bases in length" serves to modify this range. It cannot expand the scope of the range to encompass probes longer than those defined in claim 56. The claim further limits the subject matter of claim 56 in defining probes with a minimum of 15 bases in length.

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it is relevant as prior art under 35 U.S.C. §§102 and 103. No evidence has been presented that any of the probes claimed are anticipated or obvious based on full nucleic acid sequences found in nature.

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Issue 7: Whether claims 47, 48, 53 and 55-58 are obvious in view of Accession NO: A14565 in view of the Dyson Publication

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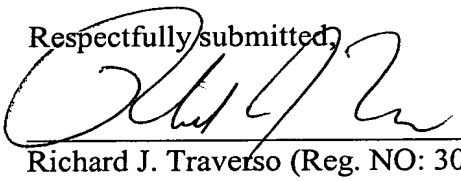
(IX) Conclusion

For the reasons stated above, Appellants respectfully submit the subject matter of the pending claims is novel and unobvious over the cited references and the specification in claims satisfy the requirements of 35 U.S.C §112, first and second paragraph. Therefore, Appellants respectfully request the outstanding rejections be reversed.

Respectfully submitted,



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Attorney Docket NO:: CABTEC-2

Date: February 2, 2004

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APPENDIX

47. An isolated nucleic acid molecule comprising SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,

or an RNA equivalent thereof,

or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or a nucleic acid substantially complementary to said isolated molecule which is capable of hybridizing to the nucleic acid molecule under the following stringent conditions:

hybridization at 40°-65 °C for 14-16 hours in a hybridization solution at ph 7.8,

containing 0.9 M NaCl, 0.12 M Tris-HCl, 6nM EDTA, 0.1M sodium phosphate buffer,

0.1% SDS and 0.1% polyvinylpyrrolidone,

followed by three 15-minute washes at 40°-65 °C to remove unbound probes in a solution at pH 7, containing 0.075 M NaCl, 0.0075 M Na Citrate and 0.1% SDS.

48. An isolated nucleic acid molecule consisting of

SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,

or an RNA equivalent thereof,

or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

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followed by three 15-minute washes at 40°-65 °C to remove unbound probes in a solution at pH 7, containing 0.075 M NaCl, 0.0075 M Na Citrate and 0.1% SDS.

52. The isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ

ID NO: 6.

53. An isolated nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6,
or an RNA equivalent thereof,
or a nucleic acid complementary to said isolated molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

55. A probe which

a) targets *Shigella flexneri* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 3, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

b) targets *Shigella sonnei* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 4, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

c) targets *Shigella dysenteriae* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 5, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or

d) targets *Shigella boydii* comprising a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 6, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

56. A probe which

a) targets *Shigella flexneri* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 3, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

b) targets *Shigella sonnei* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 4, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

c) targets *Shigella dysenteriae* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 5, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules,

or

d) targets *Shigella boydii* consisting of a fragment greater than 10 to 40 bases in length of a nucleotide sequence SEQ ID NO: 6, an RNA equivalent thereof, or a nucleic acid complementary to said molecule, capable of base-pairing according to the standard Watson-Crick complementarity rules.

57. A probe as in claim 55 which comprises 15-25 bases in length.

58. A probe as in claim 56 which comprises 15-25 bases in length.